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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/635,710	08/05/2003	Richard J. Yarwood	RPS6017C2	1897

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LEGAL DEPARTMENT - INTELLECTUAL PROPERTY
DUBLIN, OH 43017

EXAMINER	
SOROUSH, ALI	
ART UNIT	**PAPER NUMBER**
1616	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/635,710	YARWOOD ET AL.	
	Examiner	Art Unit	
	Ali Soroush	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 24-39 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 24-39 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 25-27 and 35-37 recites the limitation "according to claim 1" in the first line of each claim. There is insufficient antecedent basis for this limitation in the claim. The claims are dependent on cancelled claims. For purposes of examination it is assumed that the claims are dependent on claim 24.

Claims 28-32 recites the limitation "according to claim 4" in the first line of each claim. There is insufficient antecedent basis for this limitation in the claim. The claims are dependent on cancelled claims. For purposes of examination it is assumed that the claims are dependent on claim 27.

Claim 33 recites the limitation "according to claim 5" in the first line of the claim. There is insufficient antecedent basis for this limitation in the claim. The claim is dependent on a cancelled claim. For purposes of examination it is assumed that the claim is dependent on claim 28.

Claim 34 recites the limitation "according to claim 10" in the first line of the claim. There is insufficient antecedent basis for this limitation in the claim. The claim is dependent on a cancelled claim. For purposes of examination it is assumed that the claim is dependent on claim 33.

Claim 38 recites the limitation "according to claim 14" in the first line of the claim. There is insufficient antecedent basis for this limitation in the claim. The claim is

dependent on a cancelled claim. For purposes of examination it is assumed that the claim is dependent on claim 37.

Claim 36 is further rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim reads on the term "free domperidone base". It is not apparently clear to examiner what is meant by "free domperidone base". Applicant's specification lacks a clear definition of the term and therefore the claim is rendered indefinite.

Double Patenting

1. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claim 39 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 17 of prior U.S. Patent No. 6,726,928 B2. This is a double patenting rejection.

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 24-38 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, and 4-16 of U.S. Patent No. 6,726, 928 B2. Although the conflicting claims are not identical, they are not patentably distinct from each. Applicant claims a process for the preparation of a solid, rapidly disintegrating dosage form comprising a pharmaceutically active substance (i.e. loperamide and domperidone) in an aqueous or alcohol solvent and further comprising a carrier materials (i.e. gelatin), rendering the active substance less soluble. The process further comprises the composition being filled into a plurality of mold pockets in a film and frozen, which is further freeze-dried, or vacuum dried to remove the solvent. Applicant further claims an oral dosage form of loperamide and domperidone that has a rapid disintegration property. Patent 6,726,928 B2 claims a process for the preparation of a solid, rapidly disintegrating dosage form comprising a pharmaceutically active substance (i.e. loperamide and domperidone) in an aqueous or alcohol solvent and further comprising a carrier materials (i.e. gelatin), and further rendering the active substance less soluble **by the method of conversion of a salt to a corresponding free acid, conversion of a salt to a corresponding free base, changing salt form, formation of a hydrate and changing polymorphic form thereof**. The process further comprises the composition being filled into a plurality of mold pockets in a film and frozen, which is further freeze-dried, or vacuum dried to remove the solvent. The

Patent further claims an oral dosage form of loperamide and domperidone that has a rapid disintegration property. The Patent discloses specific methods as to the mode by which the active substance is rendered more soluble. The instantly claimed invention does not have such a limitation and therefore allows for a variety of mechanisms by which to render the active substance less soluble including pretreatment as claimed in the Patent or through the action of the solvent-carrier composition. For the foregoing reasons the instantly claimed application is rendered obvious.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 24, 26, 27, 28, 29, 31, 35, 37, and 38 are rejected under 35 U.S.C. 102(e) as being anticipated by Ecanow (US 5,382, 437, Published 01/17/1995).

Ecanow teaches a formulation that is readily dissolved, orally administered tablet, granules, powders, or liquids. (See abstract and column 4, Lines 1-2). The formulation is made by the method of mixing gelatin powder, maltodextrose, gelatin A, sucrose, and the required drug. To the mixture is added a 10% solution of ammonium in distilled water. The solution is mixed until all components are dissolved and the solution is clear. The solution is then filled into separate compartments of a mold. The mold fill is then

frozen solid. The tablets are removed from the mold and transferred to a vacuum chamber. The product is vacuum dried to sublime the 10% aqueous ammonium solvent. (See column 4, Lines 39-60). In a specific example a formulation is made comprising: gelatin powder, maltodextrin, gelatin A, sucrose, asparatine, and powdered loperamide. (See example 1). The formulation then undergoes the aforementioned method steps. Loperamide is known to have the characteristic of having a bitter taste (see abstract JP 05117149 A, Published 05/14/1993). The method of formulation of loperamide into a readily dissolving, orally administrated tablet taught by Ecanow has the inherent property of rendering the active substance less soluble and more palatable. Therefore, it would be expected that an identical process, such as that taught by Ecanow, would necessarily also render the active substance less soluble and more palatable. Further it would also be expected that the method steps would convert loperamide to the free base form by the teachings of Ecanow as it is an inherent characteristic of the method. Therefore, it would be expected that an identical method, such as that taught by Ecanow, would necessarily also render the active substance less soluble, more palatable, and convert loperamide to loperamide free base form. For the foregoing reasons the instantly claimed process and composition are anticipated.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue; and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 24, 26-30, 32-34, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gregory et al. (US 4305502, Published 12/15/1981) in view of Ince et al. (US 4657929, Published 04/14/1987).

Applicant Claims

Applicant claims a process for the preparation of a solid, rapidly disintegrating dosage form comprising a pharmaceutically active substance in an aqueous or alcohol solvent and further comprising a carrier materials (i.e. gelatin), rendering the active substance less soluble. The process further comprises the composition being filled into a plurality of mold pockets in a film and frozen, which is further freeze-dried, or vacuum dried to remove the solvent.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Gregory et al. teaches, "The invention relates to packages containing shaped articles carrying chemicals, particularly to pharmaceutical dosage forms carrying

pharmaceuticals. The shaped articles, which disintegrate rapidly in water are contained in depressions in sheets of filmic material and are enclosed by a covering sheet adhering to the filmic material." (See abstract). "The shaped articles are prepared by a process which comprises subliming solvent from a composition comprising the chemical (e.g. pharmaceutical substance) and a solution of carrier material in a solvent ..." (See column 3, Lines 21-25). "The carrier material can be any water soluble or water dispersible material that is pharmacologically acceptable or inert to the chemical and which is capable of forming a rapidly disintegratable open matrix network." (See column 2, Lines 53-57). "A particularly advantageous carrier may be formed from polypeptides such as gelatin..." (See column 2, Lines 60-62). "The solvent is preferably water but it may contain a cosolvent (such as alcohol e.g. tert-butyl alcohol) ..." (See column 3, Lines 32-34). Gregory further teaches; "A measured quantity of the composition may be added to each depression and the filmic material containing the filled material then cooled ... When the contents of the depressions are frozen the filmic and contents may be subjected to reduced pressure ...to aid the sublimation." (See column 5, Lines 12-20). "A large sheet of filmic material ... containing numerous depressions may be subjected to the freeze drying procedure and the covering sheet may then be adhered to it." (See column 5, Lines 2426). The method of formulation of a pharmaceutically active agent into a readily dissolving, orally administrated tablet taught by Gregory et al. has the inherent property of rendering the active substance less soluble and more palatable. Therefore, it would be expected that an identical process, such as that taught

by Gregory et al., would necessarily also render the active substance less soluble and more palatable.

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Gregory et al. lacks a teaching of the active substance being domperidone. Ince et al. cure this deficiency. Gregory et al. lacks an anticipatory teaching of freeze-drying to remove solvent following freezing of the composition. Gregory et al. however makes such a teaching obvious.

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

Ince et al. teaches a composition that comprises a 4-hydroxy phenethylamines and optionally other pharmaceutically active substances. (See abstract and column 10, Lines 59-64). One such example of an additional compound to be used in the composition is domperidone. (See column 11, Lines 1-11). The composition can be made into tablets and capsules further include adjuvants and carriers including gelatin. (See column 11, Lines 32-37). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Gregory et al. and Ince et al. One would have been motivated to do this so that the composition of Ince et al. could be formed into a blister pack of tablets for dispensing to a patient. Wherein the advantage of doing so by the process of Gregory et al. would "enable packages of the shaped articles to be produced in which the handling of the individual shaped articles may be eliminated until the user ... removes the product from the depression in the

package immediately prior to use." (See Gregory et al. column 4, Lines 1-6). Gergory et al. teaches the use of freeze-drying and freezing composition in the package. However, Gregory et al does not teach freeze-drying followed by the freezing step. It would have been obvious to one of ordinary skill in the art to combine the two steps. One would have been motivated to do this in order to get the additive effect of the steps in removing the solvent from the composition. For the foregoing reasons the instantly claimed process and composition are made obvious.

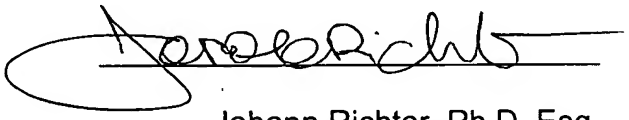
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ali Soroush whose telephone number is (571) 272-9925. The examiner can normally be reached on Monday through Thursday 8:30am to 5:00pm E.S.T.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ali Soroush
Patent Examiner
Art Unit: 1616



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